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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/782,874	02/08/2001	Michael Wassenegger	MPG-1 DIV-1	6565
110	7590	07/15/2005	EXAMINER	
DANN, DORFMAN, HERRELL & SKILLMAN 1601 MARKET STREET SUITE 2400 PHILADELPHIA, PA 19103-2307			FOX, DAVID T	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 07/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/782,874	Applicant(s) WASSENEGGER ET AL.	
	Examiner David T. Fox	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-35, 37, 48 and 65-70 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29-35, 37, 48 and 65-69 is/are rejected.
- 7) ☒ Claim(s) 70 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 April 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>20 May 2003</u> . | 6) <input type="checkbox"/> Other: _____ |

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The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's amendment of 14 April 2005 has obviated the objection to the specification regarding the incorporation of essential material. Claims 29-35, 37, 48 and 65-70 are pending and examined in the Office action below.

Claims 29-35, 37, 48 and 65-69 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, as stated on pages 3-4 of the last Office action for claims 29-35, 37, 48, 64-70 and 72-74. Claim 70 has been removed from the rejection because it does not encompass sequence variants which hybridize to the exemplified sequences under conditions of moderate stringency.

Applicant's arguments filed 14 April 2005 have been fully considered but they are not persuasive. Applicant urges that the written description rejection is improper, given the amendment of the claims to recite stringent hybridization conditions, and the allowance of claims with similar scope in the parent application. Applicant further urges that the skilled artisan would have recognized Applicant to have been in possession of the genus of sequences, given the ability of the skilled artisan to perform truncations of the exemplified sequences and determine enzymatic activity of the truncated proteins.

The Examiner notes that Applicant has amended the claims to include the hybridization conditions recited in Amasino, as suggested by the previous Examiner. However, the instant Examiner maintains that the newly recited hybridization conditions, while encompassing a higher degree of stringency than previously recited, fall short of "highly" stringent conditions. Highly stringent hybridization conditions involve a final wash of 0.1-0.2 X SSC at high temperatures, in contrast to the final wash conditions of 1-2 X SSC taught by Amasino or the 2 X SSC wash conditions as instantly claimed. Thus, the instant claims still read on moderate stringency conditions, which would recover a multitude of unrelated sequences encoding a multitude of enzymes other than RdRP enzymes.

Regarding the issued claims in the parent application, the Examiner notes that the elected invention in the parent application was drawn to the use of isolated nucleic acid sequences encoding an active RdRP protein, isolated microbial cells transformed therewith, and methods for making the RdRP protein comprising its isolation from transformed microbial cells, as argued in the Response to the Double Patenting rejection of 20 May 2003, page 7. In contrast, the instantly elected invention is drawn to isolated plant cells containing a sense construct which inhibits expression of the RdRP protein, and whole plants containing the cells (see page 8 of the Response of 20 May 2003; see also pages 2-3 of the Election of 03 September 2002). Thus, the instant claims are being interpreted as encompassing a genus of sequence fragments which are sufficient to inhibit expression of the RdRP-encoding gene. As the instant

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specification has not demonstrated any gene inhibition following plant cell transformation with sequence variants or truncations, the skilled artisan would not have recognized Applicant to have been in possession of the instantly claimed invention.

Claims 29-35, 37, 48 and 65-69 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to isolated plant cells and plants transformed with a nucleic acid sequence comprising SEQ ID NO:1 or encoding SEQ ID NO:2 for the inhibition of RdRP gene activity, does not reasonably provide enablement for claims broadly drawn to isolated plant cells or plants transformed with nucleic acid sequence variants which hybridize under conditions of moderate stringency to the exemplified sequences, for the inhibition of RdRP gene activity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, as stated on pages 4-6 of the last Office action for claims 29-35, 37, 48, 64-70 and 72-74. Claim 70 has been removed from the rejection because it does not encompass sequence variants which hybridize to the exemplified sequences under conditions of moderate stringency.

Applicant's arguments filed 14 April 2005 have been fully considered but they are not persuasive. Applicant urges that the enablement rejection is improper, given the amendment of the claims to recite stringent hybridization conditions, and the allowance of claims with similar scope in the parent application. Applicant further urges that undue experimentation would not have

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been required by the skilled artisan to obtain the claimed invention, given the ability of the skilled artisan to perform truncations of the exemplified sequences and determine enzymatic activity of the truncated proteins.

Applicant is directed to the Examiner's comments above regarding the instant claim amendments and the different inventions being claimed in the parent versus the instant divisional application. Applicant is also directed to the teachings of the newly cited art below, which clearly demonstrate the unpredictability inherent in the inhibition of gene activity when utilizing sense cosuppression, or when utilizing sequence variants, as instantly claimed.

Stam et al teach that sense cosuppression in plants, also known as gene silencing, is unpredictable, given the inability of all portions of a transgene sequence to silence endogenous genes, the unpredictable expression pattern of cosuppression across different plant tissues, the reversible nature of cosuppression, the possible dependence upon particular hotspots including random multicopy T-DNA loci, and the lack of understanding of the mechanisms of sense cosuppression (see, e.g., page 6, top paragraph of column 1 and paragraph bridging the columns; page 8, paragraph bridging the columns; page 9, column 1, top paragraph).

Kull et al teach that gene inhibition did not occur when utilizing sequence variants with as much as 65% similarity to the target gene sequence (see, e.g., page 69, Abstract; page 71, column 1, top paragraph; page 73, column 1).

Given the lack of guidance in the specification regarding the identification or evaluation of sequence variants or truncations which effect gene inhibition,

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and the lack of guidance regarding the obtention of whole plants which exhibit altered morphology as a result of the gene inhibition (as contemplated on page 25 of the specification, second full paragraph); undue experimentation would have been required by one skilled in the art to identify and isolate a multitude of sequence variants or truncations for their ability to either effect gene inhibition at the cellular level, and/or effect altered morphology in the whole plant. In the absence of successful gene inhibition and/or altered morphology, one skilled in the art would not know how to make and/or use the claimed transformed plant cells and whole plants.

The claims remain free of the prior art, given the failure of the prior art to teach or reasonably suggest isolated plant cells or plants transformed with isolated nucleic acid sequences comprising SEQ ID NO:1 or encoding SEQ ID NO:2, as stated in the last Office action.

Claim 70 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is 571-272-0795. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

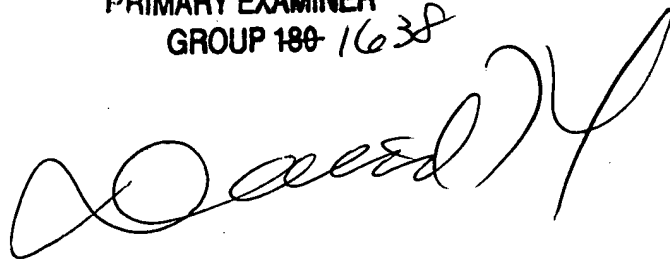
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on 571-272-0745. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

July 8, 2005

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180-1638

A handwritten signature in black ink, appearing to read "David T. Fox", written over the printed name and title.